

## **Initial Training for Sterile Compounding**

Initial training for sterile compounding must be completed, passed and documented before compounding personnel may perform any sterile compounding. This training must be for the appropriate risk level the compounding personnel will face. The initial training that is required by USP 797 is as follows:

1. Documentation of an initial written exam, which must include:
  - a. Hand Hygiene and Garbing
  - b. Aseptic Technique
  - c. Cleaning and Disinfecting
2. Documentation of Cleaning and Disinfecting Competency. This includes documentation showing cleaning and disinfecting was visually observed. Environmental Services must be trained as well if they clean or disinfect. Environmental Services is not allowed to clean the primary engineering control (hood) but is allowed to clean the rooms.
3. Documentation of a Media Fill Challenge. This media fill is to encompass the most challenging conditions the compounding personnel will face. The following documentation is required: media selection, fill volume, incubation time and temperature, inspection of filled units, interpretation of results, actions levels and corrective action, if needed.
4. Documentation of observed Gowning and Gloved Fingertip Sampling (GFS) (please note: initial GFS is different than annual GFS). The initial gloved fingertip sampling is to include 3 separate pairs of sterile gloves put on in aseptic manner on 3 different occasions. The fingertips and thumb of both hands are to be tested. Two separate agar plates (paddles are not recommended) are to be used; one agar plate for each hand. The results of each of the gloved fingertip sampling should be zero cfu's. Personnel compounding in an isolator must perform the initial gloved fingertip sampling by donning the sterile gloves in the isolator.

**\*\*There is NOT to be sterile 70% isopropyl alcohol sprayed on the sterile gloves before the test. This test ensures the compounding personnel know how to put on sterile gloves.**

Any compounding personnel who fail written or observed testing are to be immediately reinstructed and reevaluated by trained compounding personnel to correct deficiencies. Documentation of this reinstruction is required.